09/257,739

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| 09/257,739 | 02/25/99 | HIRSCHMAN | S 4493-36 |

EXAMINER

HM12/1004

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| ART UNIT | PAPER NUMBER |
|---|---|
| 1648 | 7 |

DATE MAILED: 10/04/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 7/3/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-4 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-4 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☒ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892 1page
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☒ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**



★ U.S. GPO: 1998-404-496/40517

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648.

Applicant is encouraged to file an information disclosure statement including (1) a form PTO-1449, "Information Disclosure Citation" listing patents, publications and other information material to the instant application; (2) a concise explanation of the relevance of each listed item; (3) a copy of each listed item; and (4) a disclosure of related co-pending applications. See 37 C.F.R. §§ 1.97-1.98.

Applicant's election of Group I, claims 1-4, in Paper No. 6, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse. See M.P.E.P. 818.03(a).

The Examiner acknowledges Applicant's Response to Restriction requirement and Amendment, Paper No. 6, filed July 3, 2000. In view of Applicant's Amendment, the status of the claims is as follows: Claims 5-6 have been canceled; Claims 1-4 are currently pending before the Examiner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards

as the invention. Claim 1 is vague and indefinite in the recitation "Product R" since it is entirely unclear what constitutes "Product R." The specification discloses two different methods utilizing different reagents for producing an extract designated as "Produce R" (see pages 9-11). Further, the specification clearly admits that "little is known about the chemical nature of Product R" (see page 4, line 17). Therefore, it would be unclear to one skilled in the art as to what precisely constituted "Product R" and which "Product R" is intended to be encompassed by the claimed invention. Amendment of claim 1 to more particularly point out and define "Product R" would obviate this rejection. Claim 1 is further vague and indefinite in the recitation "measuring said RT-PCR product" since it is unclear what measurement is being taken and how that measurement relates to determining down-regulation of gene expression. Amendment of claim 1 to more particularly point out and define what measurement of RT-PCR is being taken and how that measurement is used to determine down-regulation would obviate this rejection. Claim 3 is vague and indefinite in the recitation "electrophorizing said RT-PCR" since it is unclear how one would "electrophorize" (electrophorese?) a "RT-PCR". It is believed that Applicant intends to mean the "RT-PCR product" and, if so, amendment of claim 3 to recite "said RT-PCR product" would obviate this rejection. Alternatively, if this is not Applicant's intent, then Applicant is required to amend claim 3 to more particularly point out and define what is intended to be encompassed by the method step of "electrophorizing said RT-PCR." Claim 4 is vague and indefinite in the recitation "about" since it is unclear precisely what culture times are required by the claimed method. Amendment of claim 4 to delete "about" would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

**The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed invention is directed to methods for determining down-regulation of gene expression of an HIV coreceptor utilizing a composition designated "Product R." However, Product R is not defined chemically in the specification. Rather, the specification clearly admits that the composition of Product R is poorly understood (see page 4, line 17). Further, the specification actually discloses two separate methods for preparing compositions designated Product R. Yet both these methods utilize different reagents, particularly the use of either sodium hydroxide or hydrochloric acid (see pages 9-11). Thus, one skilled in the art would reasonably conclude that the Product R produced by each of these methods would possess different chemical compositions and, hence, differing chemical properties. It is not clear from the specification that both Products can be used interchangeably in methods for determining down-regulation of coreceptor gene expression.

Further, the claims do not specifically indicate what property(ies) of the RT-PCR product are measured by the methods of the claimed invention. Neither does the claimed invention specifically set forth how the measurement(s) correlate with down-regulation of coreceptor gene expression. One skilled in the art would necessarily need to know what proper measurement(s) to perform on the RT-PCR product and how to interpret those

measurements in the appropriate way to determine down-regulation of coreceptor gene expression.

Therefore, absent such specific method steps, one skilled in the art would not be able to practice the methods of the claimed invention throughout their scope with a reasonable expectation of success and without undue experimentation. Applicant should consider amending the claims to include the specific methods of preparation of the particular Product R intended to be encompassed by the claims and to amend the claims to indicate what precise property(ies) of the RT-PCR product are being measured in the claimed invention and how such measurement(s) correlate with down-regulation of coreceptor gene expression as a means to obviate this rejection.

**The claimed invention appears free of the art for the following reasons**. The closest relevant art are Hirschman, U.S. Patent No. 5,807,839 (A), Hirschman, U.S. Patent No. 5,807,840 (B), Bregman, U.S. Patent No. 5,902,786 (C), and most notably, Hirschman et al., *J. Investigative Medicine* 44(6):347-351, August 1996 (R).

Each of Hirschman (A), Hirschman (B) and Bregman (C) disclose Product R (Reticulose) which appears to be identical to the Product R of the instant application. Further, each of the references teach different clinical uses for Product R. However, none of the references teach the use of Product R in methods for determining down-regulation of a chemokine receptor.

Hirschman et al. (R), the most relevant prior art, discloses methods for studying the mechanisms of action of Product R (Reticulose) using H9 T lymphoma cells and HIV infection (see page 348, "Materials and Methods"). These methods appear analogous to the methods of the claimed invention except that Hirschman et al. does not specifically study the down-regulation of a chemokine

receptor which is a coreceptor for HIV. The Examiner notes that in the previous May and June of 1996, just prior to publication of Hirschman et al. (R), several laboratories essentially simultaneously identified CXCR4 and CCR5, chemokine receptors on the surface of T cells, as the putative coreceptors for HIV infection. Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods of Hirschman et al. (R) to study the effects of Product R on chemokine receptor expression. However, it is the Examiner's opinion that, while one of ordinary skill in the art would have been motivated to undertake studies to determine if Product R had any effect on chemokine receptor expression based on the knowledge that CXCR4 and CCR5 were known coreceptors for HIV, there exists no reasonable expectation of success in such an undertaking. It is the Examiner's opinion that the prior art did not recognize any relationship between Product R and chemokine receptor down-regulation. Therefore, while one of ordinary skill in the art would have been motivated, such an attempt would constitute an "obvious to try" situation with no reasonable expectation of success. On this basis, the Examiner holds Applicant's claimed invention free of the prior art.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also

be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.

Robert D. Budens
Primary Examiner
Art Unit 1648

rdb
October 2, 2000